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| 13. SUPPLEMENTARY NOTES   |                  |                          |                                      |   |  |
| 14. ABSTRACT<br>Over the course of the last year, the study team received IRB approval and began recruiting participants at five of the six study sites (Joint Base Lewis-McChord, Ft. Bliss, Ft. Campbell, Ft. Carson, and Ft. Stewart). As of August 31, 2012, 368 total referrals across the five active sites had been received; 179 participants had been enrolled and randomized into the study (86 participants into the STEPS UP arm; 93 participants into the optimized usual care arm); 53 participants completed the 3-month follow-up assessment; and 6 participants completed the 6-month follow-up. We are awaiting HRPO approval of our final site (Ft. Bragg); we anticipate beginning recruitment at Ft. Bragg in September 2012. Multiple amendments have been approved by the WRNMMC IRB, including an amendment that revised eligibility criteria and updated data collection forms. The study intervention has been refined to include a web-based care management support tool; nurse-assisted web-based cognitive-behavioral therapy options for PTSD and depression; a modularized telephonic cognitive-behavioral therapy option for PTSD and depression; and a preference-based stepped care approach to primary care PTSD and depression treatment sequencing. We have continued to hire and train site and centralized personnel. |                  |                          |                                      |   |  |
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## **INTRODUCTION:**

The purpose of the STEPS UP (STepped Enhancement of PTSD Services Using Primary Care) trial is to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care. We hypothesize that the STEPS UP intervention will lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; (3) costs and cost-effectiveness. We further hypothesize that qualitative data will show (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care

STEPS UP is a six-site, two-parallel arm (N = 1,500) randomized controlled effectiveness trial with 3-month, 6-month, and 12-month follow-up comparing centralized telephonic stepped-care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP will include web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred and available. The study uses sites currently running RESPECT-Mil, the Initiating PI's existing military primary care-mental health services practice network, to access site health care leaders and potential study participants at the 6 study sites.

If effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so called "15 year science to service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

## **BODY:**

The WRNMMC, RAND, RTI, University of Washington, Boston VA Research Institute (BVARI), USUHS, and HRPO IRBs have all approved the master protocol, consent form, and related study materials (20 appendices including data collection materials, manuals, impact statements, advertisements, and study personnel scripts). During the past year, the study team received final IRB approval and began recruiting participants at five of the six study sites: Joint Base Lewis-McChord (JBLM; February 2012), Ft. Bliss (March 2012), Ft. Campbell (April 2012), Ft. Carson (August 2012), and Ft. Stewart (August 2012). As of August 31, 2012, 368 total referrals across the five active sites had been received (181 referrals at JBLM, 87 at Ft. Bliss, 98 at Ft. Campbell, 1 at Ft. Carson, and 1 at Ft. Stewart). A total of 179 participants had been enrolled and randomized into the study: 86 were enrolled and randomized into the STEPS UP arm of the study (51 at JBLM, 19 at Ft. Bliss, and 16 at Ft. Campbell), and 93 into the RESPECT-MIL arm (54 at JBLM, 22 at Ft. Bliss, and 17 at Ft. Campbell). Across all five active recruitment sites, 73 potential participants were ineligible for various reasons, and 60 declined to participate. Fifty-six potential participants, at the end of this reporting period, were either scheduled or had not yet been reached. We have had several participants reach eligibility for the first 3-month follow-up assessment at JBLM, Ft. Bliss, and Ft. Campbell. As of August 31, 2012, 85 participants became eligible for the 3-month follow-up (66 at JBLM, 17 at Ft. Bliss, and 2 at

Ft. Campbell); and 53 participants have completed the 3-month follow-up assessment. We have also had 27 participants reach eligibility for the 6-month follow-up at JBLM; as of August 31, 2012, 27 participants became eligible for the 6-month follow-up, and 6 participants have completed the assessment.

Multiple amendments have been submitted to and approved by the WRNMMC IRB during the last year. In November 2011, the WRNMMC IRB approved an amendment for revisions to the data collection section of the protocol and Appendix B (Data Collection Forms). In February 2012, the WRNMMC IRB approved an amendment identifying new Site Principal Investigators at four study sites (JBLM, Ft. Campbell, Ft. Carson, and Ft. Bragg). In May 2012, the WRNMMC IRB approved an amendment revising eligibility criteria and updating data collection forms. In August 2012, we submitted an amendment to the WRNMMC IRB to allow for incentives for off-duty participation in the trial; that amendment is currently in the review process with the WRNMMC IRB. Additionally, we received amendment approvals of new site personnel (RTI-hired site coordinators, care managers, Medical Monitors, and Co-Investigators) at Ft. Bliss and Ft. Campbell. An amendment adding a new Site PI and RTI-hired full-time site coordinator at Ft. Carson has been submitted to the local IRB (Madigan IRB) in August 2012 for initial review prior to being forwarded to the WRNMMC IRB for official approval. Finally, an amendment to the Ft. Campbell package which updates Site PI contact information has been submitted to the local DDEAMC IRB for initial review prior to being forwarded to the WRNMMC IRB for official approval.

In an effort to streamline regulatory approvals at the six study sites, we have completed Institutional Agreements (IAs) with each study site's IRB. The study is currently in the regulatory review and approval phase at Ft. Bragg, the remaining study site. The local WAMC IRB and lead WRNMMC IRB have approved the Ft. Bragg site-specific materials; we are awaiting HRPO approval of the Ft. Bragg site in order to begin recruitment at our final site.

The STEPS-UP intervention has been developed and refined to include (1) a web-based care management support tool, called FIRST-STEPs; (2) a nurse-assisted web-based cognitive behavioral self management option, called DESTRESS-PC for PTSD; (3) a modularized telephonic cognitive-behavioral therapy option for PTSD and depression, called DESTRESS-T; and (4) a preference-based stepped care approach to primary care PTSD and depression treatment sequencing. A contract has been developed between the Henry M. Jackson Foundation and Ultrasis, the developer of 'Beating the Blues,' a web-based therapy for depression that will be used in the STEPS UP trial; the contract has been approved by both Ultrasis and the Henry M. Jackson Foundation and final signatures have been obtained. We have trained all seven care managers (six site care managers, one centralized care manager) to use Beating the Blues in the past year. Additional preparation in the past year has refined our recruitment strategy, finalized measures, refined final study methods, developed data collection procedures and forms, produced key materials (manuals, training materials, forms), and clarified safety procedures including inclusion criteria, consent procedures, and confidentiality protections. Agreements addressing data use and sharing and publication are nearing completion.

Study investigators continued to participate in multiple routine weekly conference calls and other communications as necessary to ensure timely completion of all tasks. At the request of Dr. Jordan Irvin (CDMRP Science Officer), we have developed and submitted detailed timelines for regulatory approval and recruitment projections; we continue to update those documents to reflect current projections. We have also submitted updated SOW's that are under review.

During the past year, the STEPS UP team conducted site visits at Ft. Campbell, Ft. Bragg, and Ft. Stewart to initiate intervention awareness and training for primary care and behavioral health providers, clinic nurses and clerical staff, and RESPECT-Mil personnel. Additionally, the STEPS UP team conducted two “kick off” site visits to JBLM and Ft. Bliss prior to starting recruitment. In April 2012, the STEPS UP team held a two-day training event for the seven study care managers at the DHCC location in Silver Spring, MD. The training included care manager skills training and discussions about study recruitment and enrollment. We have initiated the hiring process for centralized study personnel during the past year; we have hired one full-time centralized care manager, two part-time psychologists to deliver the DESTRESS-T phone therapy intervention and serve as on-call clinicians for our emergency protocol, and one part-time psychiatrist to provide telephonic consultation and treatment plan recommendations to nurse care managers and serve as an on-call clinician for our emergency protocol. We will continue hiring and training centralized study personnel during the next quarter. The DSMB, Stakeholder, and Scientific Advisory Groups are established, and we will convene these groups next quarter as well.

In the past year, RTI designed and launched the study web portal, including secure web-based study instrumentation, materials for site coordinators, and other study tools; we continue ongoing routine maintenance and evaluation of this site, as well as refinement of plans for the recruitment process at each study location. We have developed telephone interview and paper and pencil versions of the follow-up instruments. We have also trained site coordinators at each study site regarding interaction with prospective participants, logistics for working with local care providers, and other process-oriented items; site coordinators have been hired at all six study sites. During the past year, RTI has submitted a number of amendments to its internal IRB regarding the use of incentives when appropriate; minor changes to inclusion/exclusion criteria; participant contact methods and timing; and minor changes to instrumentation for purposes of usability, clarity, and decreasing participant burden.

In the past year, RAND has refined the qualitative interview protocols and emergency procedures for the qualitative portion of the study; the qualitative interviews for this project have begun. RTI is sharing identifying information on every 5th patient enrolled in the study with RAND, as permitted in the consent forms, and RAND is contacting those individuals to recruit them to participate in the interviews. RAND is filling cells as designated in the SOW to interview individuals early in the project, middle of the project, and late in the project, in both the STEPS Up and RESPECT-Mil conditions. Once recruited, each individual is interviewed 3 times during the course of their participation in the study. To date, early-phase patient and Nurse Care Facilitator interviews have begun at 3 sites (Joint Base Lewis-McChord, Fort Bliss, and Fort Campbell). We have invited 10 individuals to participate, have completed 7 interviews (with 1 hard refusal and 2 that we were unable to reach). We have interviewed all 3 Nurse Care Facilitators eligible at this time. We plan to begin middle-phase interviews with patients at these 3 sites in the near future, as well as to begin qualitative interviews with Nurse Care Facilitators and study patients at the sites that are starting up. RAND has contributed to the final measures so that appropriate inputs for the costs and cost-effectiveness analyses will be gathered. RAND investigators continue to be involved in planning meetings, site visits, and conference calls.

BVARI investigators have continued to participate in weekly conference calls to discuss the overall study design, treatment development (e.g., web-based self-management intervention, phone-based therapy), recruitment strategies, and to provide supervision and oversight of the telehealth approaches to care. In the past year, BVARI collaborators have modified DESTRESS-

PC for STEPS UP trial use and developed the phone therapy (called DESTRESS-T) for trial use to include training materials, manuals, and treatment workbooks. The telephone therapy and related materials have been modified for trial use; the therapy is a broad-based ideographic modularized approach to telephone therapy that entails ten therapeutic modules that are disseminated to patients and therapists with the purpose of being used in conjunction with phone-based therapy. BVARI collaborators have trained the two half-time centralized psychologists to deliver the telephone therapy, and continue to provide supervision and training for the phone therapy. In addition, STEPS UP care managers have been trained to manage DESTRESS-PC, and BVARI has provided continued feedback and support in this phase of care manager training. Additionally, we have continued training for behavioral activation and motivational interviewing with the care managers.

During the past year, University of Washington collaborators have refined and developed training for the STEPS UP trial intervention and have developed working drafts of the care management manual. They have also initiated more intensive supervision related to care management practices across all study sites. University of Washington investigators attend weekly telephone conferences to contribute to care manager coaching, therapy development, FIRST-STEPS enhancements, and general study implementation; they also continue to attend the University of Washington STEPS UP internal team meeting that is held approximately once each quarter. Furthermore, the University of Washington investigators

Customization of the FIRST-STEPS web-based care management software for the STEPS UP trial is ongoing but for practical purposes FIRST-STEPS is up and running; ongoing modifications will not hold up initiation of the trial or threaten the fidelity of intervention or the validity of trial results.

We plan to begin data collection at our remaining study site, Ft. Bragg, in September 2012. We will continue to pay very close attention to site-specific enrollment and retention across all study sites. During the next quarter, we will continue to ensure compliance with all IRB administrative requirements and meet with IRB chiefs and HRPO representatives to coordinate an efficient process for ongoing regulatory submission and approval. We will also continue with ongoing care manager training and coaching at each site with weekly individual staffing and group coaching calls.

#### **KEY RESEARCH ACCOMPLISHMENTS:**

There are not yet any clear scientific findings resulting from this research as we are still in the data collection phase. Results are expected in June 2015.

#### **REPORTABLE OUTCOMES:**

There are no reportable outcomes at this time, as the study is still in the data collection phase.

#### **CONCLUSION:**

There are no conclusions to report at this time, as the study is still in the data collection phase.

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## **APPENDICES:**

N/A

## **SUPPORTING DATA:**

N/A